DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 9th, 2009 has been entered.

2. Applicant's amendments and remarks, received on October 9th, 2009, have been fully considered by the examiner. Claims 1-6 and 8-20 are currently pending with claims 1, 6 13 and 18 amended and claim 7 cancelled. Applicant's amendment to claim 18 obviates the previously filed rejection under 35 U.S.C. 112, 2nd paragraph of claims 18-20. The following is a complete response to the October 9th, 2009 communication.

Claim Objections

3. Claim 1 is objected to because of the following informalities: the Examiner suggests amending line 13 of the claim to read "...is configured to receive the electrically conductive liquid..." to better enhance the clarity of the claim.. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. Claims 1-6 and 8-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the claim, upon entry of the amendment filed October 9th, 2009, has been amended to read in lines 6-10 "the treatment electrode comprising one of an elastically

stretchable and an unfoldable surface element that defines a separate interior space, that is enclosed by an auxiliary body that hydraulically separates the interior space from the surface element, to which an internal pressure can be applied to expand said surface element and thereby said treatment electrode". This recitation is however, unclear and confusing rendering the scope of the claim unascertainable. Specifically, the structural relationship of each of the portions of the device (i.e. surface element, interior space and auxiliary body) is unclear and due to this lack of clarity, it is further unclear how or to what the recited structural characteristics relate. As currently written, the limitations presented therein appear to the Examiner to each be referenced to the surface element. The Examiner would resultantly consider the surface element needing to 1) define a separate interior space, 2) be enclosed by an auxiliary body that hydraulically separates the interior space from the surface element and 3) have an internal pressure applied to expand the surface element/treatment electrode.

In light of this proffered interpretation, it would further be unclear how, with the surface element defining a separate interior space, the auxiliary body by then enclosing the surface element (with enclosing taken by its plain meaning of "to close in: surround" taken from http://www.merriam-webster.com/dictionary/enclose) would then also hydraulically separate the surface element from the interior space. It would appear for the hydraulic separation to occur, the surface element would have to enclose the auxiliary body or in other words, the auxiliary body would need to be placed within the surface element as a layer between the surface element and the interior space. It is noted that such a limitation was present in previously pending claim 13 in the claims filed April 30th, 2009, but the current recitation proffered in claim 1 for at least the

reasons above fails to invoke such a structural relationship. Claims 2-6 and 8-20 are rejected due to their dependency on claim 1. Appropriate correction is required.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-6 and 8-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claim 1, in the rejection of the claim under 35 U.S.C. 112, 2nd paragraph above, it has been noted that as the claim is currently written, the Examiner is considering the surface element needing to 1) define a separate interior space, 2) be enclosed by an auxiliary body that hydraulically separates the interior space from the surface element and 3) have an internal pressure applied to expand the surface element/treatment electrode. It has further been pointed out that in light of this proffered interpretation, it would further be unclear how, with the surface element defining a separate interior space, the auxiliary body by then enclosing the surface element (with enclosing taken by its plain meaning of "to close in: surround" taken from http://www.merriam-webster.com/dictionary/enclose) would then also hydraulically separate the surface element from the interior space. It would appear for the hydraulic separation to occur, the surface element would have to enclose the auxiliary body or in other words, the

auxiliary body would need to be placed within the surface element as a layer between the surface element and the interior space.

It is the Examiner's position that the specification as currently presented fails to set forth support for the auxiliary body to enclose the surface element but rather for the opposite to be the case. Such can be seen in at least figure 15 of Applicant's drawings and the associated disclosure in the specification referring to figure 15. Claims 2-6 and 8-20 are rejected due to their dependency on claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. Claims 1, 6, 8-13, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Swanson et al (US Pat. No. 5,797,903).

Regarding claim 1, Swanson discloses an apparatus (system **10**) comprising a first three-dimensional treatment electrode (electrode body **20** in conjunction with electrode **30**, see figures 11-12) that can be expanded to various states of expansion during use (various states occurring from expansion from collapsed state to expanded state, see col. 5; 12-18) and is capable to conduct an HF coagulation current into said tissue (see disclosure throughout patent), the treatment electrode being formed such that by one of continuous and stepwise expansion of said electrode it can be kept in constant electrical contact with the tissue during coagulation (electrode body **20** being expanded continuously from a collapsed to expanded state to maintain contact with tissue, see at least col. 5; 12-18) and comprising one of an elastically stretchable and an unfoldable surface element (electrode body **20** which enlarges/expands as internal pressure builds within) that defines a separate interior space (see figure 4, space indicated inside electrode body **20** indicated at **38**; likewise with the embodiment in figures 11-12). Swanson further

discloses for the inclusion of an auxiliary body (integrally formed plurality of bladders **64** with surface element as in col. 18; 44-54) which hydraulically separates the interior space from the surface element (bladders **64** are sealed and communicate with only the porous sections of the electrode body **20**, see col. 18; 44-57) and also discloses that a pressure internal to the surface element can be applied to expand said surface element and thereby said treatment electrode (conductive fluid supplied to bladders **64** which are internal of electrode body **20**, see figures 11 and 12). Additionally, Swanson discloses the inclusion of a liquid supply through which an electrically conductive element can be delivered to the surface element wherein the surface element is configured to receive the electrically conductive fluid from the liquid supply (see lumens **66** with conductive fluid flow supplying the fluid to the electrode body **20**, col. 18; 47-50).

Regarding claim 6, Swanson discloses the inclusion of a current supply device (radiofrequency generator **40**, signal wire **32**) capable of delivering said HF coagulation current to said treatment electrode in such a way that said HF treatment current conducted to the liquid that is passing through the treatment electrode (see col. 6; 15-26).

Regarding claim 8, Swanson discloses the surface element to be in the form of a sphere (see figures 11-12).

Regarding claim 9, Swanson discloses the treatment electrode to be constructed in the form of a balloon catheter (see figures 11-12 and col. 5; 12-18 describing balloon-like expansion of body **20**).

Regarding claim **10**, Swanson discloses for the surface element to be capable of being filled with said electrically conductive liquid (see col. 5; 11-18 and col. 6; 15-48 and col. 18; 44-54).

Regarding claim 11, Swanson discloses the electrically conductive fluid to be comprised of a viscosity modifying substance (see col. 11; 53-59).

Regarding claim 12, Swanson discloses for the treatment electrode to be made of a thermally stable material in the form of one of a film, a felt and a woven fabric (see col. 7; 66 – col. 8; 34).

Regarding claim 13, Swanson discloses for the surface element (electrode body **20**) to be constructed in several layers (inner layer being the outer surface of bladder **64** contacting layer of electrode body **20**; outer layer being the electrode body **20**) such that in an inner layer electrically conductive liquid directed towards an outer surface of the element and in an outer layer electrically conductive liquid can be directed perpendicular to the outer surface of the element (conductive fluid directed from interior of balloon through inner layer as defined about towards outer layer and outer layer allowing the transport of a little amount of fluid, see col. 8; 50-56, perpendicular to outer surface).

Regarding claim 15, Swanson discloses the electrode to be capable being supplied with a cutting current (electrode body **20** in conjunction with electrode **30**).

Regarding claim 16, Swanson discloses the thermally stable material is comprised of tetrafluoroethylene (see col. 7; 66 – col. 8; 5).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 2-4 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (US Pat. No. 5,797,903).

Regarding claim 2, Swanson discloses that each of the integrally formed bladders of the embodiment in figure 12 are controlled independently such that they are expanded dependent upon the desired geometry of the balloon. Swanson further discloses the inclusion of a frequency generator **40** with an included controller **42**. While Swanson fails to specifically disclose the controller controlling the degree of expansion of the treatment electrode dependent on the coagulation current, it would have been obvious to one of ordinary skill in the art at the time the invention was made that the embodiment of figure 12 functioning as disclosed in col. 18; 44-57 would function as such. Each of the bladders **64** being controlled for a desired geometry would require each bladder desired to contact the tissue thereby allowing for the disclosed transfer of

energy by ionic transfer to be controlled by a control device such that the treatment electrode would be inflated to a degree corresponding to the coagulation current.

Regarding claim 3, Swanson discloses the controller **42** capable of adjusting current density between the treatment electrode and the tissue (see col. 6; 8-14).

Regarding claim 4, Swanson discloses that the controller **42** would be capable of adjusting current density independent of the degree of expansion (such as when the energy is switched off and the electrode body is completely collapsed in order to be removed).

Regarding claim 17, Swanson discloses for the inclusion of a third layer to the exterior of the electrode body **20** in the form of a coating (see col. 11; 39-46). In the presence of a coating on the exterior of the electrode body **20**, the inner layer of claim 13 will remain the inner layer, the outer layer would now be considered the partition layer and the coating would be the outer layer. While Swanson is silent in regards to the partition layer being more or less permissive to the passing of liquid flow therethrough, it would been an obvious design consideration to provide the partition layer with a greater resistance than the inner layer. Taking in consideration of the construction of Swanson, the electrode body **20** is being used to control fluid passage by adjustment to pore sizes and materials. One of ordinary skill in the art would readily recognize that it would not be advantageous to prevent the flow of fluid from getting to the electrode body **20** for example, by making the bladder **64** be of higher resistance to fluid flow in comparison to the electrode body **20**.

11. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (US Pat. No. 5,797,903) as applied to claim 1 above, and further in view of Lennox et al (US Pat. No. 5,545,195).

Regarding claim 5, Swanson discloses a liquid-supply device (lumen **34**, port **36**) through which electrically conductive fluid can be delivered to the treatment electrode but fails to disclose a measurement device to detect the state of expansion of the three-dimensional body. Lennox discloses an analogous device containing a three-dimensional body which can be expanded to a plurality of expanded states containing at least one electrode. Lennox further discloses a measurement device to detect the state of expansion of the three-dimensional body (syringe **224** and its displacement, see col. 4; 2-12). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide such a fluid supply and monitoring device as that of Lennox in conjunction with the device of Swanson in order to both provide fluid to the three-dimensional body of Swanson and adequately assess the level of expansion of the three-dimensional body. Additionally, the provision of monitoring the expansion of the three-dimensional body of a device as Swanson and Lennox is well known in the art and such monitoring ensures the three-dimensional body is expanded to a safe level, not exposed to excessive amounts of pressure and does not apply excess pressure to the body lumen or space in which it is inserted.

12. Claim 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (US Pat. No. 5,797,903) as applied to claim 6 above, and further in view of Koblish et al (US Pat. No. 6,937,885 B2).

Regarding claim 14, Swanson fails to disclose a suction device provide to suck away fluid. Koblish discloses a similar device as that of Swanson comprising a first three-dimensional treatment electrode (inflatable therapeutic element **14** with non-porous region **30**, porous region **26** and in relation with electrode **32**) that can be expanded to various states of expansion during

use (various states occurring from expansion from collapsed state to expanded state) and is capable to conduct an HF coagulation current into said tissue, the treatment electrode being formed such that by one of continuous and stepwise expansion of said electrode it can be kept in constant electrical contact with the tissue during coagulation (inflatable therapeutic element **14** filled with various levels of pressure to maintain tissue contact, see col. 10; 9-30) wherein the treatment electrode comprises one of an elastically stretchable and an unfoldable surface element (inflatable therapeutic element **14** which enlarges/expands as pressure is increased, see col. 10; 9-30) that defines a hydraulically separate interior space (see figure 3, internal space of inflatable therapeutic element **14**) to which an internal pressure can be applied to expand said surface element and thereby said treatment electrode. Koblish further discloses for a suction device to be provided that sucks away liquid (fluid delivery device **72** in conjunction with ventilation lumen **58** removing fluid from the therapeutic element (see col. 9; 30 – col. 10; 9). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the suction device of Koblish in combination with the device of Swanson to provide for a means of removing fluid contained within the treatment body **20** when the device is to be collapsed and removed from the body.

13. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Phan et al (US Pat. Pub. 2003/0130572 A1) in view of Swanson et al (US Pat. No. 5,797,903)

Regarding claim 1, Phan discloses an apparatus comprising a first three-dimensional treatment electrode (see figures 4-5, porous electrode **64**) that can be expanded to various states of expansion during use (during inflation from a collapsed state to an expanded state) and is capable to conduct an HF coagulation current into said tissue (RF energy, see paragraph [0070]),

the treatment electrode being formed such that by one of continuous and stepwise expansion of said electrode it can be kept in constant electrical contact with the tissue during coagulation (see paragraphs [0059]-[0060], continuous expansion to an expanded state) but fails to disclose the specific structure of the balloon as claimed. Swanson discloses an apparatus (system **10**) comprising a first three-dimensional treatment electrode (electrode body **20** in conjunction with electrode **30**, see figures 11-12) that can be expanded to various states of expansion during use (various states occurring from expansion from collapsed state to expanded state, see col. 5; 12-18) and is capable to conduct an HF coagulation current into said tissue (see disclosure throughout patent), the treatment electrode being formed such that by one of continuous and stepwise expansion of said electrode it can be kept in constant electrical contact with the tissue during coagulation (electrode body **20** being expanded continuously from a collapsed to expanded state to maintain contact with tissue, see at least col. 5; 12-18) and comprising one of an elastically stretchable and an unfoldable surface element (electrode body **20** which enlarges/expands as internal pressure builds within) that defines a separate interior space (see figure 4, space indicated inside electrode body **20** indicated at **38**; likewise with the embodiment in figures 11-12). Swanson further discloses for the inclusion of an auxiliary body (integrally formed plurality of bladders **64** with surface element as in col. 18; 44-54) which hydraulically separates the interior space from the surface element (bladders **64** are sealed and communicate with only the porous sections of the electrode body **20**, see col. 18; 44-57) and also discloses that a pressure internal to the surface element can be applied to expand said surface element and thereby said treatment electrode (conductive fluid supplied to bladders **64** which are internal of electrode body **20**, see figures 11 and 12). Additionally, Swanson discloses the inclusion of a

liquid supply through which an electrically conductive element can be delivered to the surface element wherein the surface element is configured to receive the electrically conductive fluid from the liquid supply (see lumens **66** with conductive fluid flow supplying the fluid to the electrode body **20**, col. 18; 47-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the balloon of Swanson in place of that of Phan to provide for a combined device which can be expanded to selected geometries dependent on the intended treatment site. Additionally, one of ordinary skill in the art could accomplish the substitution using routine known construction methods available.

14. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phan et al (US Pat. Pub. 2003/0130572 A1) in view of Swanson et al (US Pat. No. 5,797,903) as applied to claim 1 above, and further in view of Kordis (US Pat. No. 5,823,189).

Regarding claim 18, Phan discloses the device as shown in the rejection of above claim 1. Phan further discloses the inclusion of a second three-dimensional treatment electrode (basket **50** with electrodes **56**) that is capable of conducting an HF coagulation current into said tissue (through electrodes **56**). Both Phan and Swanson fail to specifically recite the expanding of the second three-dimension treatment electrode to various states. In the document which Phan incorporates by reference with specific regard to the basket structure, Kordis discloses for the basket catheter to consist of a three-dimensional electrode which is expanded to various states by one of continuous or stepwise expansion (see col. 5; 47- col. 6; 28). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made that the device of Phan, specifically using the basket catheter disclosed in Kordis, would function as claimed to both be expanded to various states and conduct HF current to tissue.

Regarding claim 19, Kordis discloses for the second treatment electrode to be expandable/collapsible by the placement of pressure by a sheath on the splines of the basket defining an interior space (sheath **40**, see col. 6; 20-28). While Phan fails to specifically recite that the interior spaces of said first and second treatment electrodes can be placed under pressure independently and expanded to different degrees, it would have been obvious to one of ordinary skill in the art at the time the invention was made that the two structures of Phan, utilizing two different deployment methods, fluid pressure and mechanical force, would function independently of one another and be individually controllable by the user to effectuate a desired level of contact between the target tissue and the first or second treatment electrode.

Regarding claim 20, Phan discloses for the first and second treatment electrodes to be arranged co-axially along a central axis of said apparatus (see figures 4 and 6a).

Response to Arguments

15. Applicant's arguments filed April 30th, 2009 have been fully considered but they are not persuasive.

In response to Applicant's argument on page 7 of the Remarks that Swanson fails to disclose each of the limitations in instant claim 1, the Examiner respectfully disagrees. Applicant's attention is first drawn to the rejection of the claims under 35 U.S.C. 112, 2nd paragraph. Since the desired structural relationship of each of the parts of the apparatus as well as what structural characteristics are tied to each structure is unclear, the Examiner has interpreted the claim to invoke what has been supported and described in the specification as well as the previously pending claims. However, such an interpretation was given the broadest reasonable interpretation afforded to one of ordinary skill in the art in light of the specification

since again, a clear recitation does not appear in the instant claims. In interpreting the claim as such, it remains the Examiner's position that the embodiment of Swanson displayed in figures 11 and 12 containing a plurality of integrally formed bladders with the electrode body still meets a plurality of the claim limitations. In light of this newly proffered interpretation, each of the rejections above have been changed to more accurately reflect this interpretation. Furthermore, since Applicant's remarks in reference to this newly added limitation in claim 1 and in Swanson only quotes the limitation and does not give any further insight as to what was intended by Applicant, it is the Examiner's position that the above rejections are proper.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD HUPCZEY, JR whose telephone number is (571)270-5534. The examiner can normally be reached on Monday - Friday, 9 A.M. to 5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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